510(k) SUMMARY FOR THE TITANIUM CANNULATED INTERFERENCE SCREW

JUN 2 5 2002

510k #: K021030

page 1 of 1

Company: Future Medical Systems, Inc.
Address: 504 McCormick Drive, Glen Burnie, MD 21061
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Contact: Mr Patrick Janin

Date of submission: 3/28/2002

Name of device:

Titanium cannulated interference screw

Common or usual name:

Titanium interference screw

Classification:

Smooth or threaded bone fixation fastener: 888.3040

Predicate device:

K010595: Alaron Technologies, LLC.

Device intended use, description and substantial equivalence:

The titanium cannulated interference screw is tapered and has a smooth threaded design, which provides interference fixation of soft tissue grafts and bone-tendon-bone patellar grafts during cruciate ligament repair through arthroscopy or arthrotomy.

The screw comes in lengths between 20 and 50 mm and diameters between 7mm and 12mm, resulting in a screw adapted to the morphology of the graft and patient.

The titanium cannulated interference screw and the predicate device have the same overall design. In addition, the small differences in design do not affect the use, safety and effectiveness, between the device and the predicate device.

Based on these similarities and equivalences we believe our titanium cannulated interference screw and the Alaron interference screw K010595 are substantially equivalent for the interference fixation of soft tissue and Bone Tendon Bone graft in cruciate ligament reconstruction through arthroscopy or arthrotomy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2002

Mr. Patrick Janin
Manager
Future Medical Systems, Inc.
504 McCormick Drive
Glen Burnie, MD 21061

Re: K021030
Trade/Device Name: Titanium cannulated interference screw
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 28, 2002
Received: March 29, 2002

Dear Mr. Janin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 K Number: K021030

Device name: Titanium cannulated interference screw

INDICATIONS FOR USE:

To provide interference fixation of soft tissue graft and bone-tendon-bone patellar graft during cruciate ligament repair through arthroscopy or arthrotomy.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021030

(Please do not write below this Line-Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1)